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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* J. DOE, STATE OF NEW YORK *ex rel.* J. DOE, STATE of CALIFORNIA *ex rel.* J. DOE, STATE OF TEXAS *ex rel.* J. DOE, STATE OF MICHIGAN *ex rel.* J. DOE,

Plaintiffs,

v.

PROGENITY, INC.,

Defendant.

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

v.

PROGENITY, INC.,

Defendant.

COMPLAINT-IN-INTERVENTION OF THE UNITED STATES OF AMERICA

16 Civ. 9051 (LAP)

JURY TRIAL DEMANDED

Plaintiff United States of America (the "United States" or the "Government"), by its attorney, Audrey Strauss, Acting United States Attorney for the Southern District of New York, brings this action against Progenity, Inc. ("Progenity"), and alleges as follows:

PRELIMINARY STATEMENT

1. This is a civil fraud action brought by the United States (the "Government") against Progenity under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "FCA"), and the common law to recover treble damages sustained by, and civil penalties and restitution owed to, the Government, arising from Progenity's schemes to defraud the United States in connection with the submission of claims for payment to federally-funded healthcare programs.

2. As set forth more fully below, the United States alleges in this action that Progenity, a company that provides molecular laboratory testing services including prenatal testing, engaged in fraudulent miscoding and kickback schemes that resulted in Progenity improperly receiving millions of dollars from Medicaid, TRICARE (a healthcare program administered by the Department of Defense), and the Department of Veterans Affairs (the "VA") healthcare program.

3. From March 2014 through April 2016, Progenity knowingly and willfully submitted false claims for payment to Medicaid and the VA by fraudulently using Current Procedural Terminology ("CPT") code 88271 to seek reimbursement for certain cell-free DNA sequencing-based non-invasive prenatal tests ("NIPTs") that screen for genetic disorders and abnormalities when this code misrepresented the services Progenity actually provided. As a result, Progenity received payments for non-reimbursable tests, or received substantially higher payments than it was entitled to receive, for the genetic testing services provided.

4. In addition, in violation of the Anti-Kickback Statute (the "AKS"), 42 U.S.C. §§ 13320a-7b(b), Progenity knowingly and willfully induced physicians to order Progenity tests for Medicaid, TRICARE, and VA healthcare program beneficiaries by: (i) from January 2012 through March 2016, offering and providing remuneration in the form of above-fair-market-value payments, or "draw fees," to physicians or physician offices for blood specimens collected for Progenity tests; (ii) from January 2012 through December 2018, offering and providing remuneration in the form of meals and happy hours for physicians and their employees; and (iii) from January 2012 through April 2018, routinely offering to reduce or waive, and routinely reducing or waiving, coinsurance and deductible payments that federal healthcare beneficiaries were required to pay without making individualized determinations of financial need or reasonable collection efforts. Progenity submitted claims for payment that were tainted by illegal kickbacks to Medicaid, TRICARE, and the VA healthcare programs.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the claims brought under the FCA pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345, and over the remaining claims pursuant to 28 U.S.C. § 1345.

6. This Court may exercise personal jurisdiction over Progenity pursuant to 31 U.S.C. § 3732(a), which provides for nationwide service of process.

7. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) because Progenity does business in this District.

8. No official of the United States charged with responsibility to act in the circumstances knew or should have known of the facts material to the FCA claims related to the fraudulent billing practices alleged herein prior to November 2016. In July 2020, the

Government and Progenity entered into a tolling agreement, pursuant to which the parties agreed that any statute of limitations applicable to the claims at issue here would be tolled from August 31, 2019, through August 31, 2020.

PARTIES

9. Plaintiff is the United States of America and it is suing on its own behalf and on behalf of the United States Department of Health and Human Services ("HHS") and its component agency, the Centers for Medicare and Medicaid Services ("CMS"), which administers the Medicare program and is responsible for overseeing the Medicaid program; the Department of Defense, which administers the TRICARE program; and the VA.

10. Defendant Progenity is a company headquartered in California that provides molecular laboratory testing services to patients, through their healthcare providers, focusing on prenatal testing for genetic and chromosomal abnormalities. Prior to August 2013, Progenity operated under the name Ascendant MDx, Inc.

11. Relator Demetra Katsanos is a former sales representative of Progenity. On November 21, 2016, the relator filed a complaint in the United States District Court for the Southern District of New York pursuant to the *qui tam* provisions of the FCA, alleging, *inter alia*, that Progenity engaged in illegal kickback schemes to induce physicians to order Progenity tests.

BACKGROUND

I. The Anti-Kickback Statute and the False Claims Act

12. The FCA establishes treble damages liability to the United States for an individual who, or entity that, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); or "knowingly makes, uses, or causes to be

made or used, a false record or statement material to a false or fraudulent claim," 31 U.S.C. § 3729(a)(1)(B). "Knowingly" is defined to include actual knowledge, reckless disregard and deliberate indifference. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

13. In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim.

14. The AKS makes it illegal for individuals or entities to knowingly and willfully "offer[] or pay[] remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Violation of the AKS is a felony punishable by fines and imprisonment and can also result in exclusion from participation in federal healthcare programs. 42 U.S.C. § 1320a-7b(b)(2); 42 U.S.C. § 1320a-7(b)(7).

15. The AKS arose out of congressional concern that remuneration given to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect federal healthcare programs from these harms, Congress enacted a prohibition against the payment of kickbacks in any form.

16. The AKS defines remuneration to include anything of value, including "cash" or "in-kind" payments. 42 U.S.C. § 1320a-7b(b)(2)

17. As codified in the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, *codified at* 42 U.S.C. § 1320a-7b(g),

"a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]."

18. According to the legislative history of the PPACA, this amendment to the AKS was intended to clarify "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854.

19. Compliance with the AKS, 42 U.S.C. § 1320a-7b(b), is a condition of payment under Medicaid, TRICARE, and the VA healthcare program, which are defined as "Federal health care programs" under the AKS.

II. The Federal Healthcare Programs

20. ***Medicaid.*** Pursuant to the provisions of Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.*, the Medicaid program was established in 1965 as a joint federal and state program created to provide financial assistance to individuals with low income to enable them to receive medical care. Under Medicaid, each state establishes its own eligibility standards, benefit packages, payment rates, and program administration rules in accordance with certain federal statutory and regulatory requirements. The state directly pays the healthcare providers for services rendered to Medicaid recipients, including physician-based services, with the state obtaining the federal share of the Medicaid payment from accounts which draw on the United States Treasury. *See* 42 C.F.R. §§ 430.0 *et al.*

21. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid

recipient. The federal government pays to the state the statutorily established share of the "total amount expended . . . as medical assistance under the State plan." 42 U.S.C. § 1396b(a)(1).

22. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from providers of laboratory testing services, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30.

23. Medicaid claims arising from illegal kickbacks are not authorized to be paid pursuant to the PPACA, 42 U.S.C. § 1320a-7b(g). Further, such claims are not payable under state regulatory regimes.

24. Providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid rules and regulations in billing the state Medicaid program for services or supplies furnished.

25. Furthermore, in many states, Medicaid providers, including providers of laboratory testing services, must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations.

26. Many Medicaid service providers are either reimbursed directly by states on a fee-for-service basis, or through claims submitted to Managed Care Organizations ("MCOs"). States contract with MCOs to provide benefits to Medicaid beneficiaries and the MCOs receive monthly capitation payments for providing these services. Providers submit claims for payment to MCOs for services provided to Medicaid beneficiaries enrolled in the managed care plan. Claims for payment submitted to MCOs are deemed to be "claims" under the FCA since the managed care plan is a "contractor, grantee, or other recipient," the money is being used "to advance a Government program or interest," and the Government provides or has provided a portion of the money requested and/or will reimburse the MCO for a portion of the money requested. 31 U.S.C. § 3729(b)(2)(A). In their agreements with providers, MCOs require providers to comply with the rules and regulations of the Medicaid program.

27. Progenity participates in more than 30 state Medicaid Programs and has agreements with numerous MCOs.

28. ***TRICARE.*** TRICARE (formerly known as CHAMPUS) is part of the United States military's healthcare system, designed to maintain the health of active duty service personnel, provide healthcare during military operations, and offer healthcare to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military

clinics, and the benefit program, known as TRICARE. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

29. The federal government reimburses a portion of the cost of laboratory testing services under TRICARE.

30. Some TRICARE options require participating members to pay a co-pay and/or to meet a deductible. 32 C.F.R. § 199.4(f). A provider of services generally cannot, as a matter of law, waive these co-pay or deductible requirements. 32 C.F.R. § 199.4(f)(9).

31. Providers of services to TRICARE beneficiaries are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. § 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Kickback arrangements are included within the definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b), 199.9(c)(12).

32. On March 6, 2013, Progenity (then under the name Ascendant MDx, Inc.) executed a Provider Services Agreement with Humana Military Healthcare Services, the support contractor for TRICARE Management Agency, with an effective date of April 1, 2013, permitting Progenity to become a TRICARE program participating provider authorized to provide services to TRICARE beneficiaries.

33. The Provider Services Agreement states, in part, that Progenity agrees to provide healthcare services for beneficiaries in accordance with the TRICARE program regulations, polices, and procedures; understands that no payment may be made to Progenity for services rendered to beneficiaries which are not medically necessary or not otherwise a covered benefit

under the TRICARE program; and agrees to be bound by and comply with the provisions of all applicable state and federal laws and regulations.

34. ***Veterans Health Administration*.** The Veterans Health Administration ("VHA"), which is part of the VA, is the United States' largest integrated healthcare system, serving nine million enrolled veterans each year.

35. The VHA provides medical care to veterans as well as to certain dependents and spouses of veterans, and manages several healthcare benefit programs.

36. To obtain reimbursement from the VHA, providers must submit claims for payment. Providers are required to comply with applicable federal laws and regulations, including the AKS.

III. CPT Codes and Billing Process

37. In order to receive reimbursement payments from the Government for medical services covered by Medicaid, TRICARE, and the VA, a provider must submit claims for payment. These claims must contain CPT codes, which are a set of standardized medical codes developed and maintained by the American Medical Association that are used to identify and report the medical, surgical, and diagnostic procedures and services provided. The claims are required to reflect, among other things: (a) the code that accurately identifies the medical procedure or service; (b) the date the service was rendered; (c) the name of the patient who received the services; and (d) the name of the provider.

38. Government healthcare payors use CPT codes to determine both coverage, *i.e.*, if they will pay for the billed medical procedures and services, and reimbursement, *i.e.*, how much they will pay for the billed medical procedures and services.

39. Each procedure or service furnished to a patient has a specific CPT code. Further, each CPT code receives a certain level of reimbursement, which can vary depending on what other codes are billed. The amount of money a provider is paid by Government healthcare payors for a service rendered to a patient depends on which CPT codes are submitted as part of the corresponding claim.

40. When there is no existing CPT code that accurately describes a specific service or test, an unlisted or miscellaneous CPT code should be used for a provider to seek reimbursement. The manual published by the American Medical Association to provide guidance on coding explicitly states, "[d]o not select a CPT code that merely approximates the service provided. If no such specific code exists, then report the service using the appropriate unlisted procedure or service code."

41. For all codes, the service or procedure must be documented sufficiently by the provider to support any claim submitted for the service or procedure.

FACTUAL ALLEGATIONS

I. Progenity's Fraudulent Miscoding Practice

42. From March 2014 through April 2016, Progenity knowingly submitted false claims for payment to Medicaid and the VA by using CPT code 88271 to obtain reimbursement for NIPTs.

43. NIPTs are performed to detect chromosomal aneuploidy (*i.e.*, too many or too few chromosomes) through the evaluation of genetic material called cell-free DNA. To perform an NIPT, DNA from the mother and fetus is isolated and extracted using the mother's blood sample, and is screened for the increased chance of specific chromosome problems. Because NIPTs

identify X & Y sex chromosomes, patients often request tests solely for the purpose of knowing the gender of their fetus when it is a few weeks old.

44. Certain NIPTs can test for microdeletions, which are deletions of chromosomal segments too small to be identified through a microscope. Microdeletions are caused when a chromosome is missing a small piece, and depending on the size and location of the deletion, it may cause a disorder. Some payors view testing for microdeletions as being more experimental or investigational than testing for chromosomal aneuploidy, and therefore do not cover it.

45. CPT code 88271 applies to a range of fluorescence in situ hybridization ("FISH") procedures. Progenity knew that its genetic tests were cell-free DNA sequencing-based NIPTs, which are different from FISH procedures, and that CPT code 88271 did not accurately represent the tests performed. Progenity was not performing cytogenetic analysis for its tests, was not doing single-strand DNA sequencing, and was not using DNA probes, all of which are necessary components of a FISH procedure.

46. Until January 2015, there was no CPT code that was specific to NIPTs, except for the Harmony test (which was not used by Progenity). In the absence of a designated code, Progenity improperly used CPT code 88271 when seeking reimbursement for certain NIPTs, instead of the miscellaneous CPT code 81479. Progenity submitted billings under CPT code 88271 because it knew that billings submitted under the miscellaneous code were subject to closer scrutiny and were likely to be denied reimbursement or paid a lower rate of reimbursement. The reimbursement rate for CPT code 88271 during the relevant period was substantially more than the reimbursement rate for the miscellaneous CPT code 81479.

47. On January 2, 2015, a new CPT code, 81420 (Genomic Sequencing Procedures and Other Molecular Multianalyte Assays), became active. Upon its implementation, CPT code

81420 became the correct code that Progenity should have used to bill its NIPTs. However, Progenity knew that many patients who received its NIPTs did not meet one or more of the high risk factors that payors required for reimbursement for an NIPT under CPT code 81420, such as being over the age of 35 or having an ultrasound result showing an increased risk of aneuploidy. Progenity therefore continued to fraudulently bill Medicaid and the VA using the CPT code 88271 and misrepresenting the test that was actually being performed.

A. Progenity Knowingly Used a False CPT Code to Maximize the Payments Received from Medicaid and the VA.

48. Progenity was well aware that CPT code 88271 was not the correct code for billing its NIPTs but used the code anyway to maximize the payments it received from Medicaid and the VA. Prior to March 2014, Progenity billed NIPTs using different CPT codes to determine which codes resulted in reimbursement, as well as the greatest reimbursement it could receive under a particular code. Once Progenity determined that CPT code 88271 had the best results, it consistently used that code even though management knew it misrepresented the nature of the tests performed.

49. For example, as early as August 2013, Progenity's Director of Managed Care at the time stated to other managers: "My concern about using the cytogenetic code [88271] is that it is not accurate to the test being done."

50. Additionally, in November 2013, an employee at the billing company used by Progenity advised Progenity's Director of Managed Care at the time that 88271 is a "FISH code," that policies "[around NIPTs] do not list 88271 as a billable code," and that insurance companies may be paying for NIPTs under CPT code 88271 "just because it's an established CPT and the insurance companies don't really know what it's for." The billing company

employee further explained that he "would bet dollars to donuts that the insurance company does not realize what exactly it is that they are paying for . . . ."

51. Progenity weighed the risks of using the incorrect CPT code and decided to proceed with using it. In an internal December 2013 email, Progenity management mused that the risk to billing under the wrong CPT code is that the payors "could ask for the $$ back – But, we would still be able to rebill using a more appropriate code as defined by the payor."

52. In March 2014, Progenity's coding consultant unequivocally advised the company: "Coding Summary: We emphasize that CPT code 88271 is not appropriate" for NIPTs. Progenity disregarded this unambiguous advice, and continued to submit claims using CPT code 88271 because it was getting paid through that code.

53. Progenity also knew that Medicaid beneficiaries in certain states were not eligible for coverage for NIPTs. For example, Medicaid programs in some states, such as Texas, Colorado, Washington, Kansas and New York, allowed reimbursement for NIPTs only if the patient had one or more high-risk factors, such as being over the age of 35 or having an ultrasound result showing an increased risk of aneuploidy. Progenity knew that many patients did not meet the medical necessity criteria for NIPTs, and that it could circumvent those requirements by billing under CPT code 88271.

54. Similarly, Medicaid policies in some states, such as New York, Texas and Kansas, do not reimburse for NIPTs that test for microdeletions, but billing under a false CPT code enabled Progenity to receive reimbursement for these tests.

B. Progenity Continued to Falsely Bill Under CPT Code 88271 After the Implementation of a Directly Applicable CPT Code.

55. On January 2, 2015, a new CPT code, 81420, became active that was clearly the correct code to use to bill for Progenity's NIPTs. However, Progenity continued to use CPT code 88271 to maximize the payments it received from Medicaid and the VA.

56. The ongoing improper use of CPT code 88721 allowed Progenity to continue to receive reimbursements even if patients did not have one or more high-risk factors that would made them eligible for coverage. In January 2015, Progenity's Director of Managed Care at the time acknowledged that the American College of Obstetricians and Gynecologists guidelines "only support testing in HIGH risk", but that payors "will probably still pay the 88271 indefinitely if they don't understand the NIPT difference in codes . . . in short they don't know that 88271 is being used for NIPT," and that "[w]e will always probably get paid in low risk with 88271" as opposed to using CPT code 81420.

57. In September 2015, Progenity's reimbursement strategy consultant confirmed that "81420 is still the most appropriate code" for a Progenity NIPT called Verify. The consultant also advised that the most accurate coding option for NIPTs that test for microdeletions was CPT code 81479 (the miscellaneous code), but use of that code "may flag a claim for increased scrutiny and potential denial" while billing under CPT code 88271 will "allow claims to fly under the radar and obtain some incremental payment."

58. As a result of fraudulently using CPT code 88721 and misrepresenting the type of test performed when submitting thousands of false claims to Medicaid and the VA, Progenity received payments for non-reimbursable tests, or received substantially higher payments than it was entitled to receive for the genetic testing services provided. Medicaid and the VA healthcare program would not have reimbursed Progenity if it had disclosed the actual test that it was

performing, an NIPT, instead of billing under CPT code 88271 and, in effect, claiming that it was performing a FISH test.

II. Progenity's Kickback Schemes

59. Progenity induced physicians to order Progenity tests for federal healthcare program beneficiaries by engaging in the following three different schemes in violation of the AKS: (i) providing "draw fees" to physicians or physician offices for blood specimens collected for Progenity tests; (ii) providing meals and happy hours for physicians and their employees; and (iii) routinely reducing or waiving coinsurance and deductible payments that federal healthcare program beneficiaries were required to pay for costly Progenity tests.

A. Progenity Made "Draw Fee" Payments to Physicians to Induce Them to Order Progenity Tests.

60. From January 2012 through March 2016, Progenity knowingly made above-market rate "draw fee" payments to physicians or physicians' offices for the collection of blood specimens for Progenity tests performed on federal healthcare program beneficiaries.

61. Progenity entered into agreements with physicians that specified the amount the physicians would receive for each specimen.

62. The physician's office would send Progenity the number of blood specimens collected during a given month for Progenity's tests, and Progenity would pay the physician or physician's office for those draws at the agreed-upon amount on a monthly basis.

63. Progenity did not make any effort to review the information provided by physicians' practices to determine if any of the patients were federal healthcare program beneficiaries to avoid potential AKS violations.

64. The draw fees paid by Progenity exceeded the fair market value of the services performed when collecting blood specimens.

65. Progenity was aware of the fact that in 2014, Medicare's rate of reimbursement to providers was $3 per blood draw, and that amount reflected the market rate. However, Progenity frequently paid physicians $20.00 or more for each blood draw.

66. The total draw fees paid to physicians depended on the volume of blood specimens collected, so physicians would receive more money if they ordered more Progenity tests.

67. Overall, from January 2012 through March 2016, Progenity paid over $1.7 million in draw fees in order to induce orders of Progenity tests. Dozens of physicians and physician offices throughout the United States received thousands of dollars in draw fee payments from Progenity during this period**.**

B. Progenity Purchased Food and Alcohol for Physicians and Their Staff to Induce Physicians to Order Progenity Tests.

68. From 2012 through 2018, Progenity's strategy for increasing its sales included providing meals, snacks, and alcohol to physicians, as well to individuals who worked in physicians' offices. In total, Progenity expended millions of dollars on food and drinks for physicians and their staff throughout the United States during this period.

69. Sales representatives provided food and alcohol to physicians and their staff at gatherings that often involved little or no educational content. These gatherings included happy hours held at bars and other establishments, including Hooters.

70. Progenity's sales management directed sales representatives to make frequent contact, or "touches," with physicians' practices, and sales representatives were encouraged to offer meals and happy hours in order to facilitate these contacts.

71. For example, an internal presentation provided to sales representatives in the northeast region stated that the expectation was "Dinner & Happy hours with offices on a regular basis (1-2/month min)."

72. In performance reviews, sales managers set goals for sales representatives that included hosting a minimum number of dinners or happy hours for doctors and their staff per month.

73. Additionally, managers sent emails to sales representatives directing them to host dinners. For example, a December 2015 email from a sales manager to her sales representatives stated that each representative "will be expected to do a minimum of two dinners with customers in your territory each month. These can be small roundtable dinners, larger programs, one on one dinners . . . whatever you feel [sic] most beneficial for your customers. Feel free to do more, but a minimum of 2 each month."

74. Sales representatives also hosted birthday, holiday, and other parties for physicians and their staff that were held at the physician's office or at a bar or restaurant.

75. The following are examples of some of the expenses that sales representatives submitted and were approved for reimbursement by Progenity:

- May 12, 2014 expense at The Cheesecake Factory for "happy hour with dr and staff"
- December 17, 2014 expense at D Vine for "Holiday Happy Hour"
- September 9, 2015 expense for BrickTops for "happy hour"
- September 10, 2015 expense for Hotel Zaza/Hooters for "happy hour with new Dallas docs"
- December 20, 2015 expense for "Holiday lunch/Happy hour"
- May 20, 2016 expense for Del Frisco's Grille for "out to lunch/Happy hour due to main nurse last da[y]"
- June 6, 2016 expense for District Wine for "Happy Hour"
- March 12, 2017 expense for Salsa Brava for "office happy hour"

76. Additionally, to maximize the number of touches with a physician's practice, it was common practice for sales representatives to take orders for snacks and beverages, such as smoothies and lattes, and drop them off at a physician's practice.

77. Sales representatives also provided "goodies," such as M&Ms in company colors, whiskey cakes, and items from Edible Arrangements, to physicians and their staff on a regular basis.

78. The value of the food and drinks provided to specific physicians and their staff frequently exceeded the aggregate annual limits under the Stark Law. 42 U.S.C. § 1395nn.

79. For the vast majority of the relevant period, Progenity did not limit or even monitor the total amount its sales representatives spent on a physician.

80. In addition, during the vast majority of the relevant period, Progenity did not maintain accurate sign-in sheets reflecting attendance at Progenity-sponsored gatherings. Sales representatives were allowed to pay for meals for an entire physician's office, including the billing department and cleaning staff.

81. In 2015, a former sales representative located in Texas spent $65,658.00 on meals and alcohol for physicians, which Progenity approved. The sales representative also created a sign-in sheet containing the names of all of the employees in a practice and obtained their signatures. Thereafter, the sales representative would submit for reimbursement a photocopy of the sign-in sheet each time she provided food or drinks to that practice.

C. Progenity Routinely Reduced or Waived Coinsurance and Deductible Payments to Induce the Use of Progenity's Tests.

82. Some federal healthcare programs beneficiaries who receive laboratory tests, including Medicaid and Tricare beneficiaries, may be required to cover a certain portion of the payment for the test in the form of a coinsurance payment or a deductible.

83. Coinsurance payments and deductibles give patients an incentive to choose the most cost-effective therapy and are intended to avoid the billing of unnecessary services. As the HHS Office of the Inspector General, observed in a 1994 Special Fraud Alert, "[s]tudies have shown that if patients are required to pay even a small portion of their care, they will be better health care consumers, and select items or services because they are medically needed, rather than simply because they are free." *Available at* https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

84. The waiver of coinsurance or deductible payments may violate the AKS unless the waivers are not offered to solicit business, are not offered routinely, and are offered only after a good-faith determination that the beneficiary is in financial need or after making reasonable collection efforts. 42 U.S.C. § 1320a-7b; 42 U.S.C. § 1320a-7a(i)(6)(A).

85. From January 2012 through April 2018, as part of its sales efforts, Progenity routinely reduced or waived federal healthcare program beneficiaries' coinsurance and deductible payments without making the required individualized determination of financial need or reasonable collection efforts.

86. Some of the Progenity tests were costly and required significant patient payments. To market its expensive tests, sales representatives informed physicians and their staff, as well as patients, that Progenity would waive coinsurance and deductibles, or limit the patient's payment to a certain maximum out-of-pocket amount, regardless of the actual coinsurance or deductible amount. Progenity waived or reduced coinsurance and deductibles without receiving any supporting documents or additional financial information from patients.

87. Progenity often referred to the practice of limiting a patient's out-of-pocket payments as the "Peace of Mind" program.

88. Progenity used the Peace of Mind marketing program to induce physicians to prescribe, and patients to consent to, costly Progenity tests. The fact that a patient would only be required to pay a reduced or no payment was attractive to physicians because they would not receive calls from their patients complaining about bills from Progenity.

89. The maximum out-of-pocket amount a patient had to pay for a Progenity test depended on factors such as the marketing strategy being used at the time and the volume of business being provided by the physician or the physician's practice. For example, in 2014, when Progenity began to offer its Verify NIPT test, it informed physicians' practices that it was offering the test for 90 days at a maximum out-of-pocket rate of $0, which meant that the patients would not have to pay any coinsurance or deductible amount.

90. Progenity provided scripted responses for its billing department to use if a patient called about a bill, which included directing staff to simply adjust the bill down to the maximum out-of-pocket amount.

91. Progenity had agreements with several physicians that it would not collect any payments from their patients. Progenity internally used the term "Monkeys in a Barrel" or "MIB" to refer to these physician accounts.

92. Through its routine reduction or waiver of beneficiaries' coinsurance and deductible payments, Progenity induced physicians to order, and patients to submit to, Progentiy's tests.

CLAIMS FOR RELIEF

FIRST CLAIM

Violation of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1)(A))

93. The Government incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

94. The Government seeks relief against Progenity under Section 3729(a)(1)(A) of the False Claims Act.

95. Through the acts set forth above detailing Progenity's fraudulent miscoding and kickback schemes, Progenity knowingly, or acting with deliberate ignorance or reckless disregard for the truth, presented, or caused to be presented, false or fraudulent claims for payment to federal healthcare programs in connection with laboratory testing services provided by Progenity.

96. The federal healthcare programs made payments to Progenity because of the false or fraudulent claims.

97. If the federal healthcare payors had known that the claims presented for payment were for tests that were inaccurately billed or resulted from illegal kickbacks, they would not have paid the claims.

98. By reason of these false or fraudulent claims, the Government has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

SECOND CLAIM

Violations of the False Claims Act: Use of False Statements (31 U.S.C. § 3729(a)(1)(B))

99. The Government incorporates by reference each of the preceding paragraphs as if fully set forth herein.

100. The Government seeks relief against Progenity under 31 U.S.C. § 3729(a)(1)(B).

101. Through the acts set forth above detailing Progenity's fraudulent miscoding and kickback schemes, Progenity knowingly, or acting with deliberate ignorance or reckless disregard for the truth, made, used, and caused to be made and used, false records and statements material to the payment of false or fraudulent claims by federal healthcare programs.

102. Progenity made and/or caused to be made numerous false records and statements, including claims with inaccurate CPT codes and false certifications of compliance with applicable federal and state laws and regulations.

103. If the federal healthcare payors had known that the records and statements were false, they would not have paid the claims.

104. By reason of these false records and statements, the Government has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

THRD CLAIM

Unjust Enrichment

105. The Government incorporates by reference each of the preceding paragraphs as if fully set forth herein.

106. Through the acts set forth above detailing Progenity's fraudulent miscoding and kickback schemes, Progentiy has received payments to which it was not entitled and therefore

was unjustly enriched. The circumstances of these payments are such that, in equity and good conscience, Progenity should not retain those payments, the amount of which is to be determined at trial.

WHEREFORE, the Government respectfully requests judgment to be entered against Progenity as follows:

a. On the First and Second Claims (FCA violations), a judgment for treble damages and civil penalties to the maximum amount allowed by law;

b. On the Third Claim (unjust enrichment), a judgment for damages to the extent allowed by law.

c. Granting the Government costs and such further relief as the Court may deem proper.

Dated: July 21, 2020
New York, New York

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